

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR	:	Master File No. 2:12-MD-02327
SYSTEM PRODUCTS LIABILITY LITIGATION	:	
	:	MDL No. 2327

-----	:	Hon. Joseph R. Goodwin, USDJ
THIS DOCUMENT RELATES TO ALL CASES	:	
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**MEMORANDUM OF LAW IN SUPPORT OF
MOTION TO INTERVENE TO SEEK STAY AND AMENDMENT OF PTO 190**

INTRODUCTION

This matter arises as a result of the Court’s entry of Pretrial Order #190 (“PTO 190”), establishing protocols for preservation, storage and retrieval of explants and tissue samples taken from plaintiffs in the Ethicon pelvic mesh products liability litigation. The Court’s order, entered August 12, 2015 upon the agreement and stipulation of the plaintiffs and defendants, required that all such medical specimen evidence must be transferred to and held by a single third-party repository facility operated by Steelgate, Inc. in Bradenton, Florida.

Proposed intervenor SciSafe, Inc. is a medical evidence storage company that is currently storing more than 250 explanted Ethicon mesh devices on behalf of more than 20 law firms in secure, climate-controlled and monitored facilities. Application of PTO 190 to SciSafe and its clients would require transfer of those stored materials to a Steelgate, resulting in SciSafe’s loss of all current and future business connected with this litigation – amounting to hundreds of thousands of dollars in revenue lost and effectively transferred to a business competitor by order of this Court.

SciSafe, an industry leader in biological, pharmaceutical and medical device evidence storage, is an FDA-registered and audited facility fully compliant with FDA regulations and related “Good Manufacturing Practices.” It provides medical evidence storage and retrieval services in numerous litigations, including Multi-District Litigations involving IUDs, artificial hips, artificial knees and all varieties of surgical mesh, and is as qualified as Steelgate to provide storage and retrieval services in the Ethicon litigation.

For the reasons set forth below, SciSafe respectfully requests that it be permitted to intervene in this action only to the extent of securing a stay of PTO 190 as it relates to SciSafe and its clients and an amendment of the order to designate SciSafe as an approved third-party repository in the Ethicon litigation, subject to all the protocols and procedures of PTO 190.

STATEMENT OF FACTS

Proposed intervenor SciSafe, Inc. incorporates herein by reference the Certification of Garrie Richardson in support of its motion in lieu of reiterating all the relevant facts. By way of summary, however, SciSafe is a biological and pharmaceutical storage and cold-chain logistics service, created in 2010 specifically as a medical-legal storage and retrieval service with chain-of-custody security. Certification in Support of Motion, ¶¶ 1-2. SciSafe operates facilities in Cranbury, New Jersey and Billerica, Massachusetts. *Id.*

SciSafe manages storage and retrieval of thousands of pieces of medical evidence on behalf of both plaintiffs and defendants in both individual actions and mass-tort litigation, including matters involving potentially defective medical devices such as IUDs, artificial hips, artificial knees, and all types of surgical mesh; the company currently stores more than 250 mesh explants on behalf of more than 20 law firms in the Ethicon Pelvic Repair System products

liability litigation. *Id.* at ¶ 3-4. SciSafe is the only FDA-registered and regulated medical evidence storage facility in this market, offering the highest levels of evidence storage, security and chain-of-custody documentation in compliance with FDA regulations and related Good Manufacturing Practices *Id.* at ¶ 5. The company has a highly trained staff and state-of-the-art facilities with redundant safeguards for sample preservation. *Id.* at ¶¶ 6-8.

Requiring transfer of materials stored at SciSafe to another repository will result in unnecessary additional costs to all parties – not only in the costs to the litigants of transport and transfer to Steelgate, but also in a significant loss of both present and future business to SciSafe, which could amount to hundreds of thousands of dollars effectively transferred to a business competitor. *Id.* at ¶¶ 9, 12. By contrast, allowing SciSafe to continue operating as an approved third-party repository in the Ethicon litigation would assist in ensuring competitive pricing for the parties’ storage and retrieval costs. *Id.* at ¶ 9.

Finally, transferring materials from SciSafe to another repository more than 1500 miles away adds unnecessary risk to the preservation and security of the medical evidence through travel hazards, while storing all such materials in a single location runs the additional risk of losing the entirety of the MDL’s evidence in the event of a catastrophic incident at the site. *Id.* at ¶¶ 10-11.

LEGAL ARGUMENT

I. SciSafe Is Properly Permitted To Intervene In This Litigation And To Obtain Relief Through A Stay And/Or Amendment Of PTO 190.

The Federal Rules of Civil Procedure provide that “[o]n timely motion, the court must permit anyone to intervene who ... claims an interest relating to the property or transaction that is

the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2).

As the Fourth Circuit explained, an intervenor under the rule must satisfy four requirements:

First, the intervenor must submit a timely motion to intervene in the adversary proceeding. Second, he must demonstrate a "direct and substantial interest" in the property or transaction. Third, he has to prove that the interest would be impaired if intervention was not allowed. Finally, he must establish that the interest is inadequately represented by existing parties.

I/M/O Edward Richman, 104 F.3d 654, 659 (4th Cir 1997); *see also CSX Transportation, Inc. v. United States Cruises, Inc.*, 1993 WL 89813, *2, decision referenced in a "Table of Decisions Without Reported Opinions" 989 F.2d 482 (4th Cir. 1993) ("To secure intervention of right in a district court proceeding, the moving party must file a timely request and satisfy the requirements for interest, impairment of interest, and inadequate representation.).

A. SciSafe's Motion Is Timely.

SciSafe submits that its motion is timely in that PTO 190 was entered by the Court on August 12, 2015, directing transfer of designated materials within 60 days of the entry of the order. This motion for a stay and amendment of PTO 190 is filed within that 60-day period, and no materials have yet been transferred from SciSafe to Steelgate. *Cf. Houston General Ins. Co. v. Moore*, 193 F.3d 838, 840 (4th Cir. 1999) (motion to intervene was untimely where it was filed two months after entry of final judgment in the district court and time to appeal had expired, although even "entry of final judgment is not an absolute bar to filing a motion to intervene.").

B. SciSafe Has A Direct and Substantial Interest in the Property or Transaction.

Rule 24 does not specify what type of interest a party must have to intervene as a matter of right, but the Supreme Court has recognized that “ ‘[w]hat is obviously meant ... is a significantly protectable interest.’ ” *Teague v. Bakker*, 931 F.2d 259, 261 (4th Cir.1991) (quoting *Donaldson v. United States*, 400 U.S. 517, 531 (1971)). The Supreme Court has held that an impact on economic competition provides a sufficient interest to justify intervention under the rule. *Cascade Natural Gas Corp. v. El Paso Natural Gas Co.*, 386 U.S. 129 (1967); *see also Feller v. Brock*, 802 F.2d 722 (4th Cir. 1986) and *Utahns for Better Transp. v. United States Dep’t of Transp.*, 295 F.3d 1111 (10th Cir.2002) (threat of economic injury is sufficient to allow intervention).

Although SciSafe has no vested interest in the *outcome* of the Ethicon litigation as a whole, its interest in the Court’s regulation of discovery and the preservation and storage of the medical evidence in the MDL is direct and substantial, as it is the very business in which it is engaged. SciSafe currently holds more than 250 specimens in storage for more than 20 law firms involved in the Ethicon mesh MDL, and offers its services to potential Ethicon litigants who have yet to select a storage and retrieval provider. Storage and retrieval of evidence in the Ethicon mesh litigation represents a significant revenue stream for SciSafe.

C. SciSafe’s Interest Would Be Impaired if Intervention Was Not Allowed.

It is beyond question that SciSafe’s business interest in the storage and retrieval of medical evidence in the Ethicon mesh litigation would be impaired if it were not permitted to intervene and seek relief in the form of an amendment to PTO 190. The effect of the Court’s

entry of PTO 190 in its current form is to deprive SciSafe of hundreds of thousands of dollars in both present and future business related to the Ethicon litigation and to transfer those revenues to a direct business competitor. There is no evident justification for this result, since SciSafe's facilities, staff and service are at least equal, if not superior, to those of Steelgate, and SciSafe is willing to comply with all protocols and procedures of material preservation, storage and retrieval outlined in PTO 190.

D. SciSafe's Interest Is Inadequately Represented by Existing Parties.

For purposes of intervention, a movant need only demonstrate "that representation of his interest 'may be' inadequate." *Trbovich v. UMWA*, 404 U.S. 528, 538 n. 10 (1972). For this reason, the Supreme Court has described the applicant's burden on this matter as "'minimal.'" *Teague*, 931 F.2d at 262 (quoting *Trbovich*, 404 U.S. at 538 n. 10).

Here, neither plaintiffs nor defendant in the Ethicon mesh litigation are seeking the same result as SciSafe, let alone representing the company's interest in any way. Indeed, by requiring the parties to use only Steelgate as the sole designated repository of medical evidence, both plaintiffs and defendant have actively worked against SciSafe's interest in crafting PTO 190. In this case, there could be no presumption that the movant's interest is adequately represented by either side in the litigation. "In such circumstances, it is perfectly sensible to require a more modest showing of inadequacy before granting intervention of right since an existing party is not likely to adequately represent the interests of another with whom it is at cross purposes in the first instance." *Stuart v. Huff*, 706 F.3d 345, 352 (4th Cir. 2013).

CONCLUSION

For all of the foregoing reasons, proposed intervenor SciSafe, Inc. requests that this Court

grant its motion to intervene in this litigation; stay the implementation of PTO 190 with respect to transfer of materials currently stored by SciSafe; and amend PTO 190 to designate SciSafe as an approved third-party repository for the storage and retrieval of explanted materials for all purposes in this litigation.

Respectfully submitted,

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